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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,432	04/21/2004	Saverio Carl Falco	BB1167B	7009

23906 7590 05/31/2006

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WILMINGTON, DE 19805

EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/829,432

Applicant(s)

FALCO ET AL.

Examiner

Phuong T. Bui

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/23/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment filed March 23, 2006. Claim 12-20 are pending and are examined in the instant application. **This action is made FINAL.** All rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Since SEQ ID NO:3 encoding SEQ ID NO:4 was first disclosed in Application No. PCT/US99/15809, Applicant has priority benefit of the filing date of July 13, 1999.

Applicant's Petition to Correct Inventorship under 37 CFR 1.48(a) has been granted. Inventor Tarczynski has been added.

### *Sequence Listing*

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:3 and its corresponding amino acid sequence SEQ ID NO:4, it is unclear what region of SEQ ID NO:3 encodes SEQ ID NO:4. Clarification is required.

In Applicant's response of March 23, 2006, Applicant indicated that a sequence error eliminated a nucleotide at position 406 resulted in a frameshift that eliminated the putative start methionine of the full-length cDNA sequence (p. 5, Remarks). However, according to Applicant's Appendix C, it would appear that the sequencing error actually eliminated nucleotide "A" at position 379 of SEQ ID NO:3, which corresponds to position 406 of clone p0016ctscj40rb.seq. It is noted that nucleotide sequence SEQ ID NO:3 appears to correspond to amino acid sequence SEQ ID NO:4. Inserted nucleotide "A"

Art Unit: 1638

at position 379 of SEQ ID NO:3 would change the Proline at position 123 of SEQ ID NO:4 to Histidine. Since the clone was not deposited, none of Applicant's original disclosure verifies the error, and the error is not an obvious one, Applicant is not entitled to correction of the sequencing error. Furthermore, since the sequencing error resulted in elimination of the start methionine, there is no evidence that the ATG codon at position 137 of SEQ ID NO:4 is the start codon of the full-length sequence. In addition, Applicant indicated on page 6 of the Remarks that SEQ ID NO:4 is NOT a complete protein.

Positions 2-1030 of SEQ ID NO:3 encode SEQ ID NO:4.

***Claim Rejections - 35 USC § 112, first paragraph***

3. Claims 12-15 and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:3 encoding SEQ ID NO:4, does not reasonably provide enablement for sequences reciting less than 100% sequence identity to a sequence encoding SEQ ID NO:4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is maintained for reasons of record. As previously stated, claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining enzyme activity.

Art Unit: 1638

Since Applicant only traverses the enablement rejection with regard to lack of utility (which has been withdrawn in view of Applicant's persuasive arguments), this rejection is maintained.

4. Claims 12-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record. As previously stated, claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. Additionally, the "comprising" language reads on a complete protein, which Applicant is not in possession of (p6, Remarks, March 23, 2006).

Since Applicant only traverses the written description rejection with regard to lack of utility (which has been withdrawn in view of Applicant's persuasive arguments), this rejection is maintained.

#### **Remarks**

5. No claim is allowed. SEQ ID NO:3 encoding SEQ ID NO:4 is free of the prior art. Claims 16 and 17 would be allowable if rewritten in independent form with the "consisting of" language in place of the "comprising" language. The closest prior art teaches a sequence from *Catharanthus roseus* having 52% sequence identity with Applicant's SEQ ID NO:4 (Table 4). It is understood by the Office the recited Clustal

Art Unit: 1638

alignment method uses the default parameters set forth on page 17, lines 10-12 of the specification.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

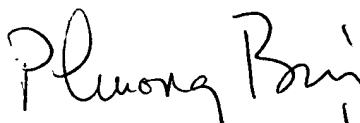
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

05/29/06

  
Phuong T. Bui 5/29/06  
Primary Examiner  
Art Unit 1638